DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 1 2011

Re: DEXILANT (previously KAPIDEX)
Patent Nos. 6,462,058;
6,664,276; and 6,939,971
Docket Nos.: FDA-2009-E-0237
FDA-2009-E-0238
FDA-2009-E-0239

The Honorable David Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This letter is in regard to the applications for patent term extension for U.S. Patent Nos. 6,462,058; 6,664,276; and 6,939,971 filed by Takeda Pharmaceutical Company Limited, under 35 U.S.C. § 156. The human drug product claimed by the patents is DEXILANT (previously KAPIDEX) (dexlansoprazole), which was assigned new drug application (NDA) No. NDA 22-287.

DEXILANT was approved on January 30, 2009. A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4).

Our records further indicate that DEXILANT represents the first permitted commercial marketing or use of the drug product, as required by 35 U.S.C. § 156(a)(5)(A). As noted in the November 8, 2010, letters from your Office of Patent Legal Administration, the Federal Circuit recently concluded that, for the purposes of patent term extension, "'product' as used in [35 U.S.C.] section 156(a) is the active ingredient present in the drug," and that a purified enantiomer is a different drug product from a previously approved racemate.[1] The active ingredient in DEXILANT, dexlansoprazole, is the R-enantiomer of a racemate, lansoprazole, that FDA has previously approved for commercial marketing or use as Prevacid, NDA 20-406 (approved May 10, 1995). However, FDA has not previously approved dexlansoprazole itself, or any salt or ester of dexlansoprazole, for commercial marketing or use. Therefore, in accordance with the analysis of the Federal Circuit's decision in *Ortho-McNeil v. Lupin* set forth in the November 8, 2010, letters, for purposes of patent term extension, DEXILANT is the first permitted commercial marketing or use of the "product," as defined under 35 U.S.C. § 156(f)(1)-(2).

[1] *Ortho-McNeil Pharm., Inc. v. Lupin Pharms., Inc.*, 603 F.3d 1377, 1381 (Fed. Cir. 2010).

We have also reviewed the dates contained in the applications and have determined the regulatory review period for DEXILANT. The total length of the regulatory review period for DEXILANT is 1,675 days. Of this time, 1,278 days occurred during the testing phase and 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 2, 2004.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 2, 2004.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 31, 2007.

   The applicant claims December 28, 2007, as the date the new drug application (NDA) for DEXILANT (NDA 22-287) was initially submitted. However, FDA records indicate that NDA 22-287 was submitted on December 31, 2007.

3. The date the application was approved: January 30, 2009.

   FDA has verified the applicant's claim that NDA 22-287 was approved on January 30, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patents, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Douglas P. Mueller
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